

# EXHIBIT

# 10

**DOCUMENT PRODUCED IN NATIVE FORMAT**

**DOCUMENT PRODUCED IN NATIVE FORMAT**

# **AmerisourceBergen**

**2009 National Healthcare Conference**

**State & Federal Regulatory Issues**

**That Impact The Pharmaceutical Industry**

**August 8, 2009**

# Chris Zimmerman, CPP, CFE

- Vice President, Corporate Security & Regulatory Affairs, AmerisourceBergen Corporation
- 25 years of healthcare industry experience, the last 20 years with AmerisourceBergen Corporation in Regulatory Affairs and Corporate Security
- Active member of HDMA's Government & Public Policy Council, Regulatory and Government Affairs Committee, Chairman of Anti-Counterfeit Task Force
- Active member and Chairman of the American Society for Industrial Security's Pharmaceutical Security Council's Membership Committee
- Board Certified Protection Professional and Fraud Examiner



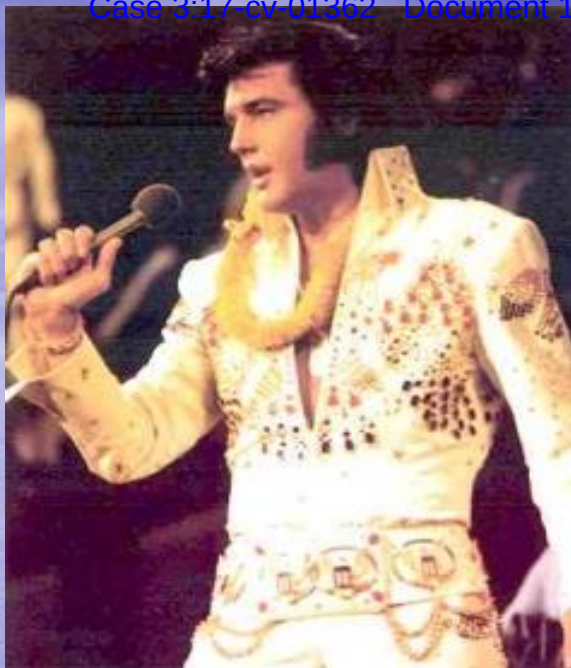
# Background

- Audience
  - Geography
  - History
- Perspective
- Process
- Handouts

# Objectives

- Increase Awareness to the Dramatic Increase in Prescription Drug Abuse in the U.S.
- Understand ABC's Diversion Control Program
- Offer "Best Practices" Solutions for DEA Compliance
- Discuss Current Legislative & Regulatory Initiatives:
  - **Ryan Haight Online Pharmacy Consumer Protection Act**
  - **Prescription Drug Disposal**
  - **Pedigree**
  - **Methamphetamine Production Prevention Act**
  - **FDA Risk Evaluation and Mitigation Strategies (REMS)**
  - **Marketing of Unapproved Narcotics**





# Prescription Drug Abuse in the U.S.

- In 2007, an estimated 2.7 Million persons aged 12 or older used an illicit drug for the first time. Three fifths were younger than age 18 when they first used.
- Non-medical use of prescription drugs ranks **second only to marijuana** as the most prevalent category of drug abuse.
- In both 2006 and 2007, an estimated 5.2 Million persons aged 12 or older were current non-medical users of prescriptions pain relievers.\*



# Prescription Drug Abuse in the U.S.

- 2008 Annual Survey by the University of Michigan
  - 386 public and private schools
  - 46,348 students
- Prescription/over-the-counter drugs account for 7 out of 11 of the most frequently abused drugs
- Nearly 1 in 10 High School Seniors have abused Vicodin
- Nearly 1 in 20 High School Seniors have abused Oxycontin



# Prescription Drug Abuse in the U.S.

- “In 2008, 3,000 people died in Florida from prescription drug overdoses – **three times the deaths** attributable to illegal drugs. The problem is multifaceted: teens raiding medicine cabinets; those in chronic pain taking too much of their prescription; addicts who doctor shop to secure a new prescription for their next high.”
- “In the second half of 2008, the top 50 doctors dispensing oxycodone nationwide were all in Florida, including 33 in Broward County, according to DEA.”

\*St. Petersburg Times – June 3, 2009

# Hydrocodone Growth vs Population Growth 1990 – 2007\*

- Between 1990 and 2007
  - 21% growth in population
- Between 1990 and 2007
  - 280% increase in distribution of hydrocodone
- **99%** of all hydrocodone manufactured in the World is consumed in the United States.

\*Drug Enforcement Administration



# Current Schemes – Pain Clinics

- East Coast Hub: Florida Pain Clinics
  - Heavy concentrations in Miami-Dade, Broward and West Palm Beach counties
  - MD visit and dispense from same location
  - Primarily cash; \$200 for initial visit, \$150 for follow-up visit
  - \$825 - \$950 for cocktail (Soma, Valium & Oxycodone)
  - \$1.50 - \$2.00 per pill from non-affiliated pharmacy
  - \$3.00 - \$4.00 per pill from pain clinic's in-house pharmacy
  - Average 120 – 180 pills per prescription
  - Out of state patients
    - Distribution to identified states of Maryland, Virginia, Kentucky, Tennessee and Ohio for **\$30-\$40 per pill**
    - DTOs transport patients to clinics every two weeks to meet with as many doctors as possible during 2-3 day timeframe

\*Drug Enforcement Administration

# Pain Clinics

- Houston Hub
  - Distribution networks to neighboring states: LA, AR & MS
  - Prescriptions being filled in Texas, then carried to state of origin
  - Medical visits range from \$85 - \$100
  - Most commonly written is hydrocodone
  - Average \$55 to fill Rx for 120 pills
  - Closed system (Rx is faxed to partnering pharmacy)
  - Partnering pharmacy sells narcotics at reduced rate to avoid extra scrutiny
  - Owners of pain clinics are usually non-DEA registrants
  - Pain clinics hire a medical director who is a DEA registrant
    - Signs blank prescription pads
    - Shows up at clinic once every few days

\*Drug Enforcement Administration



# Pain Clinics

- West Coast Hub: Los Angeles
  - Distribution networks north along the west coast to Seattle
  - To Las Vegas, Houston, Louisiana, Memphis, and Atlanta; U-Hauls and express mail services
  - Similar to Florida pain clinics; however clinics issue prescriptions which are filled at “approved” pharmacies (partnered with physicians)
  - Patients travel from all over California and out of state to visit “Pill Mill” clinics; regularly transported in by bus/van by DTOs.

\*Drug Enforcement Administration



# Doctor Shopping

- Individual Patients
  - Target Physicians
    - Obtain prescriptions from multiple physicians
    - Physicians willing to prescribe controlled substances over extended period of time with little or no follow-up
  - Target Pharmacies
    - Utilize multiple pharmacies to fill orders
    - Pharmacies known to dispense controlled substances without asking questions

\*Drug Enforcement Administration

# Doctor Shopping

- Trafficking Organizations
  - Recruit individuals to obtain narcotics
    - Targets often have legitimate medical conditions (favorite targets: seniors, nursing homes, homeless shelters)
    - With cooperating physician or staff, patients never see physician
      - False identification, obtained from consenting individuals, used to “create” medicals records and obtain scripts
    - Pay patients for their narcotics and services
  - Target physicians
    - Those known to prescribe with little or no follow-up
    - Sympathetic to patients’ medical situation
    - Commonly long distance from patients’ residence
  - Well organized
    - Often provide transportation of patients to/from physicians and pharmacies

\*Drug Enforcement Administration



# Prescription Fraud

- Fake prescriptions
  - Often highly organized
  - Use real physician name and DEA number
    - Contact information false or “fake office”
    - Organizations set up actual offices with contact information and staff (change locations often to avoid detection)
  - Prescription printing services utilized
- Stolen prescriptions
  - Forged
  - “Smurfed” to large number of different pharmacies

\*Drug Enforcement Administration

# DEA Regulatory Update

- Recent DEA Enforcement Actions
  - Cardinal settles w/DEA **(\$34M)**
  - McKesson settles w/DEA **(\$13.7M)**
  - Rite Aid Corporation settles w/DEA **(\$5M)**
  - Masters Pharmaceutical settles w/DEA **(\$500,000)**

***Masters Pharmaceutical, Inc. Sold 4.2 Million Doses of Hydrocodone, Phentermine and Alprazolam without Reporting Sales to DEA***



# Changes In DEA

- Diversion Investigator vs. Drug Enforcement Agents
- Increase in field investigations
- Distributors are viewed as a “choke point” for diversion control by DEA
  - Over 66,000 DEA Registered Pharmacies
  - Over 1 Million DEA Registered Practitioners
  - Less than 900 DEA Registered Distributors (**“big three” = 90%**)
- Increased focus on sales associates and front line distributor employees (customer service, drivers, etc.)



# Regulatory Responsibility

Title 21 of the Code of Federal Regulations:

**1301.71(a)** – “**All applicants and registrants** shall provide **effective controls** and **procedures** to guard against theft and diversion of controlled substances.”

# ABC's Diversion Control Program

- "Know Your Customer" Due Diligence
- Order Monitoring Program (OMP)
- Investigations
- Education and Training



# ABC's Diversion Control Program

On a monthly basis ABC conducts approximately:

- 4,000 – Suspicious Order Reviews
- 100 – NCDD Investigations
- 20 – Suspicious Order Investigations

# Healthcare Distribution Management Association (HDMA)

## Industry Compliance Guidelines: Reporting Suspicious Orders & Preventing Diversion of Controlled Substances

### HDMA Guidelines – October 2008

- Know your customer Due Diligence
- Monitoring for Suspicious Orders
- Suspend/Stop an Order of Interest Shipment
- Investigation of Orders of Interest
- File Suspicious Order Reports with DEA
- Employees, Training and SOPs.

### ABC DCP – April 2007

- Know your customer Due Diligence
- Monitoring for Suspicious Orders
- Suspend/Stop and Order of Interest Shipment
- Investigation of Orders of Interest
- File Suspicious Order Reports with DEA
- Employees, Training and SOPs
- Customer education, Model P&P, CSRA visits, On-going enhancements to OMP.



# New Customer Due Diligence

- **"Know Your Customer"** Due Diligence investigations completed on all new Retail and Wholesale Accounts.
- New Account Questionnaire
- Information Verification
- Internet Search
- On-site visit includes photographs inside and out (or physical description of premises)















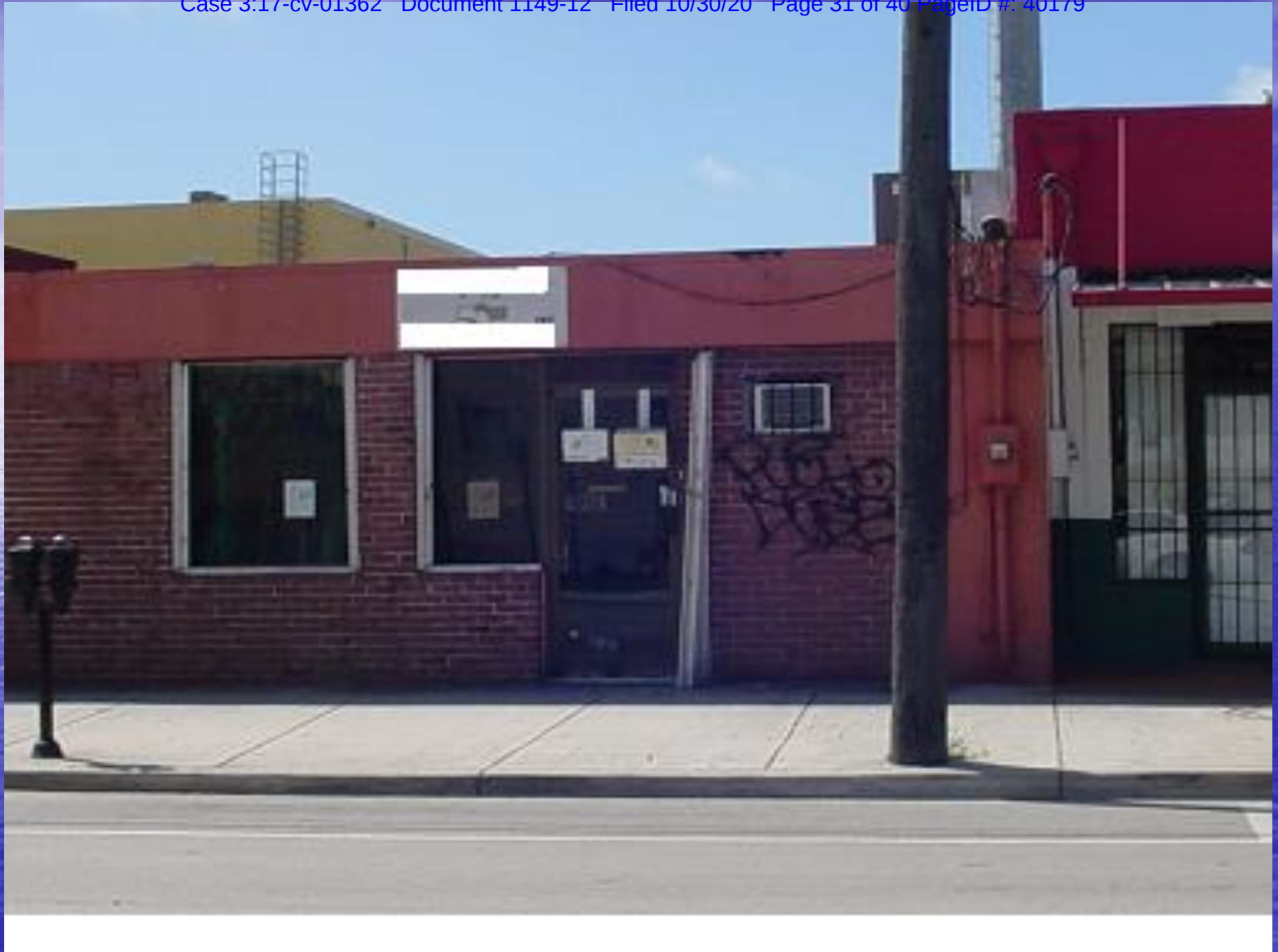




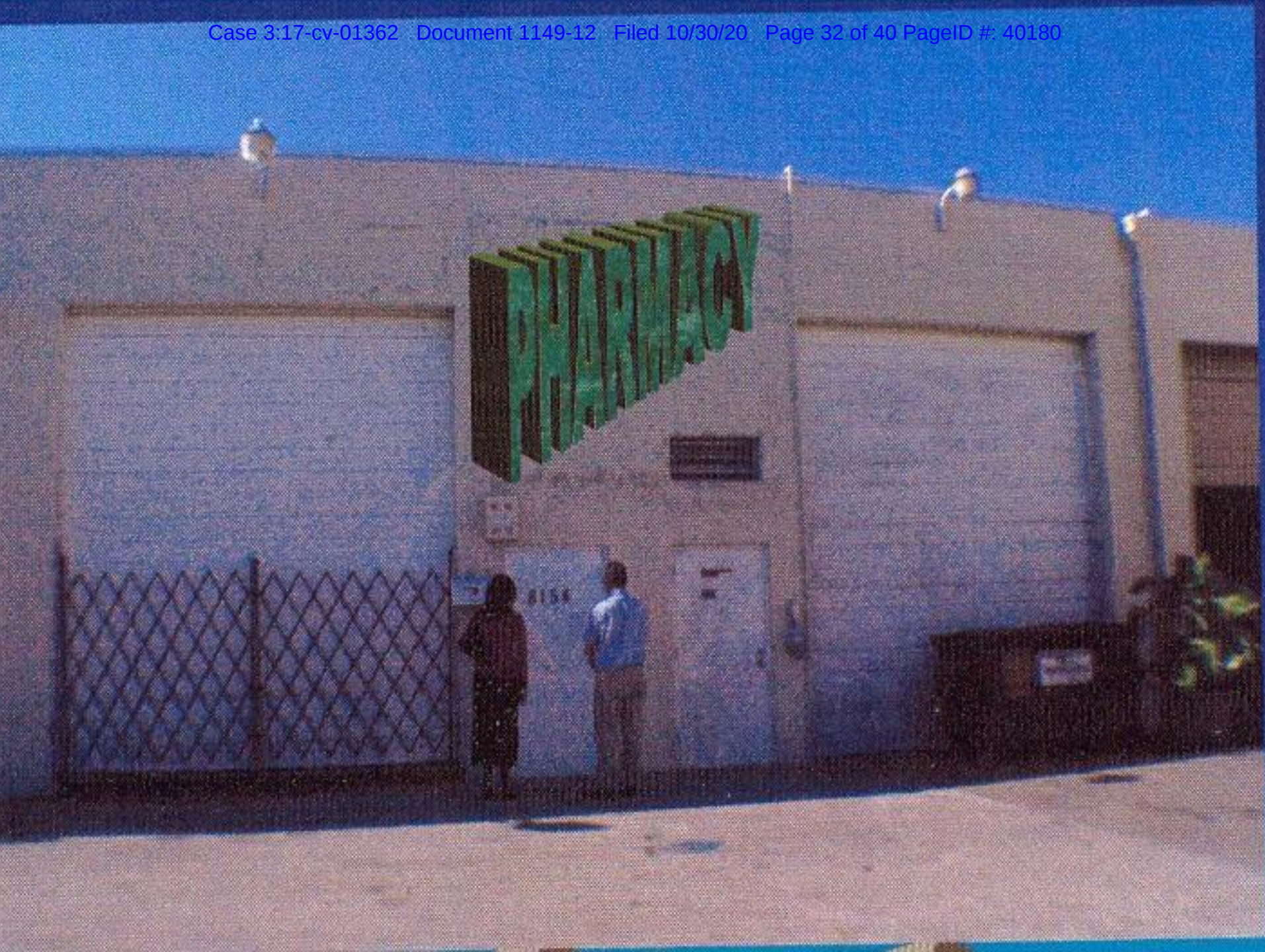














# Residential Commercial Mortgages

**PHARMACY  
COMING SOON**



FINE SPAIN  
Medicine Center

FLORIDA  
SUNCOAST









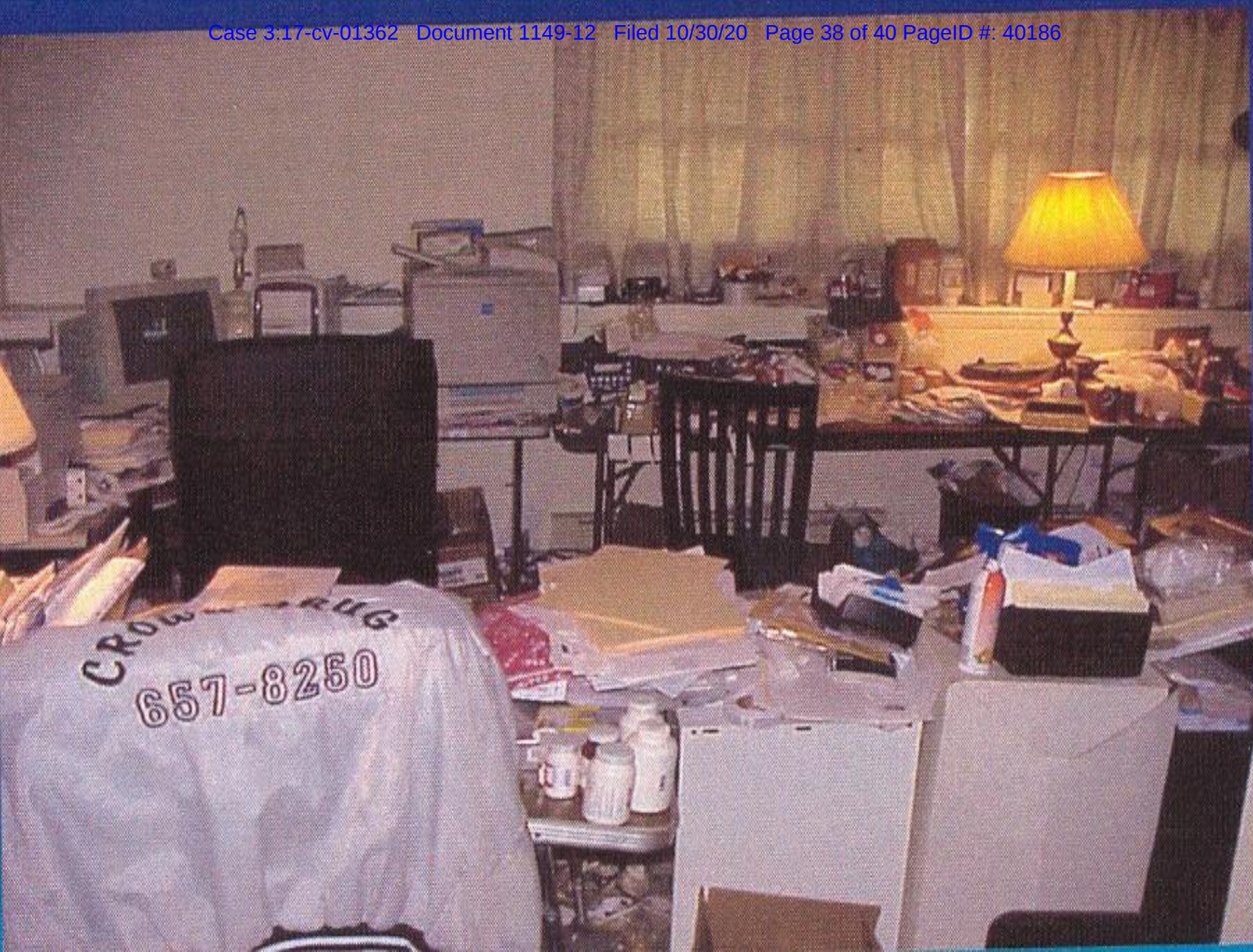














# ABC's Diversion Control Program

- "Know Your Customer" Due Diligence
- **Order Monitoring Program (OMP)**
- **Investigations**
- **Education and Training**

# Order Monitoring Program (OMP)

- Customers classified in OMP according to DEA business activity.
- Total monthly dollar volume = customer size
- Thresholds = average of CS products purchased by like classified customers + 300%.
- Thresholds are continually evaluated based on variables such as business model, location, specialties, etc.